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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,763	02/21/2002	Jonathan A. Eppstein	19141.0016U2	4362

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1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

*/b*

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/084,763

Applicant(s)

EPPSTEIN ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7, 8, 32, 51, 55-60, 63 and 64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7, 8, 32, 51 and 63 is/are allowed, *except for the consideration of the reference issue. Cor*
- 6) ☒ Claim(s) 55-60 is/are rejected.
- 7) ☒ Claim(s) 64 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office Action is responsive to the Amendment filed January 27, 2004. The Examiner acknowledges the amendments to claims 32 and 58, as well as the cancellation of claims 1-6, 9-31, 33-50, 52-54, 61 and 62. Claims 7, 8, 32, 51, 55-60, 63 and 64 are currently pending.

#### ***Claim Objections***

2. Claim 64 is objected to because of the following informalities: in line 15, "d)" apparently should read --(d)--. Appropriate correction is required.

3. The indicated allowability with the exception of the consideration of the interference issue of claims 55-60 is withdrawn in view of the newly discovered reference(s) to Dombrowski ('513) and Douglas et al. ('983). Rejections based on the newly cited reference(s) follow. Upon review of the applications in the chain of continuity for the instant application, it has been determined that a vacuum device or a device mechanically inducing a positive pressure are not initially disclosed until at least U.S. Application Serial No. 08/776,863 filed September 5, 1997. In view of the foregoing, the earliest effective priority date for the vacuum device in the instant application is considered to be September 5, 1997.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Dombrowski ('513). Dombrowski teaches an apparatus for obtaining biological fluid, including blood and interstitial fluid, for diagnostic testing. The apparatus includes a device **29** for forming an opening in an area of skin suitable for extracting a sample and a vacuum device **20,38,50** for introducing a vacuum onto the area of skin so as to enhance biological fluid flow, including blood and interstitial fluid, from the skin.

Claims 55 and 56 of the instant application further recite that the vacuum device is capable of controlling the pressure level and/or timing of the vacuum, and is capable of maintaining the vacuum at a desired pressure level. However, the specification of the instant application does not disclose exactly how the vacuum device of the present invention is capable of controlling the pressure level and timing of the vacuum or of maintaining the vacuum at a desired pressure level; and is only enabling for these limitations in so much as a conventional pump, syringe device, diaphragm or other source of negative pressure (page 46, first full paragraph of the present specification) would be known to be capable of performing such

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functions. Since the vacuum device of Dombrowski includes a barrel, a gasket and a plunger similar to a conventional syringe device, the vacuum device of Dombrowski is considered to be capable of controlling the pressure level and timing of the vacuum and of maintaining the vacuum at a desired pressure level.

6. Claims 57-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Douglas et al. ('983). Douglas et al. teach an apparatus for obtaining a biological fluid for diagnostic testing. The apparatus 10 includes a first device 26 for forming an opening in the skin suitable for extracting a sample of biological fluid and a second device 70,72 for introducing a positive pressure to the area of skin to assist in the fluid flow from the opening. The second device is capable of controlling the timing and the amount of pressure on the area of skin by means of triggers 38,50 and motor 88. The apparatus also includes a vacuum device 26 for introducing a vacuum on to the area of skin to enhance fluid flow from the opening. The second device is capable of controlling the timing of the vacuum by turning the vacuum on or off by means of triggers 38,50. The biological fluid is blood or interstitial fluid (col. 6, lines 49-52).

***Allowable Subject Matter***

7. Claims 7, 8, 32, 51, 63 and 64 are allowable over the prior art of record except for the consideration of the interference issue.

***Response to Arguments***

8. Applicant's arguments/remarks that, in view of the amendments to claim 32 and 58 as well as the cancellation of claims 1-6, 9, 10, 38, 39, 49, 50, 52-54, 61 and 62, there are no further issues believed to be outstanding in the present application have been considered but are moot in view of the new grounds of rejection. Applicant's request for an interference is acknowledged, but is also moot in view of the withdrawal of the indicated allowability, with the exception of the consideration of the interference issue, of claims 55-60 in view of the newly discovered references to Dombrowski and Douglas et al. set forth hereinabove.

***Conclusion***

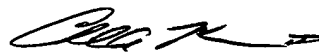
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tankovich (418) teaches a sampling device including a laser and a vacuum device. Grace et al. ('229) teach an apparatus for the collection of interstitial fluids using positive pressure and a vacuum. Douglas et al. ('871) teach a blood and interstitial fluid sampling device.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

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March 26, 2004